

REMARKS

Claims 1, 3 and 7 are pending in this application. Claim 1 has been amended herein to rephrase the claimed embodiment of the invention. Accordingly, no new matter has been added by these amendments.

Applicants have previously provided information regarding copending U.S. applications that possibly contain subject matter similar to the present claims.

The outstanding rejections are addressed individually below.

1. *Rejection of claims 1, 3, and 7 under 35 U.S.C. § 112, second paragraph*

Claims 1, 3, and 7 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Office Action states that the newly added language “with the cultured fibroblast cells contained with the synthesized extracellular matrix layer” is indefinite because it is unclear whether the cells are present merely during the process of making or are positively required in the construct that is grafted to close the opening.

Claim 1 has been amended herein to rephrase the claim language. Applicants submit that the new language “grafting a bio remodelable cultured connective tissue construct that comprises an extracellular matrix layer and cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members to close the opening in the annulus fibrosis” is definite. This language clearly indicates that the cultured connective tissue construct that is grafted comprises cultured fibroblast cells.

Applicants submit that this rejection has been overcome. Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

2. *Rejection of claims 1, 3, and 7 under 35 U.S.C. § 103(a) over Stovall in view of Doillon et al. or Feree.*

Claims 1, 3, and 7 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stovall in view of Doillon *et al.* or Feree. Applicants respectfully traverse this rejection.

While Applicants do not acquiesce in the propriety of the rejection of the characterization of the references, Applicants provide the following nonlimiting remarks.

Claim 1 was previously amended to incorporate the general substance of claim 5, which had been indicated allowable if rewritten in independent form. The instant Office Action states that the "indicated allowability of previous claim 5 is withdrawn in view of a new interpretation of previous claim 5 In particular, the language of lines 10-14 of amended claim 1 beginning at 'which is synthesized . . . ' is being treated as a product-by-process. For this reason, the claims only clearly require a layer of extracellular matrix for the construct as claimed." Applicants respectfully disagree.

Claim 1 is a method claim, which necessarily includes some structure as part of the method, not a product-by-process claim. However, in order to expedite prosecution of this application, claim 1 has been amended to rephrase the language that is interpreted as allegedly product-by-process. Applicants submit that claim 1 as amended is not a product-by-process claim.

Accordingly, as the withdrawal of the indication of allowability was based on the new interpretation of previous claim 5 (now claim 1) as product-by-process, Applicants submit that claim 1 as amended and claims 3 and 7 dependent thereon are not obvious over Stovall in view of Doillon *et al.* or Feree. Although Feree was not previously cited, Applicants submit that Feree does not teach or disclose the claimed embodiments of the invention. These references do not teach, either alone or in combination, the claimed embodiments of the invention.

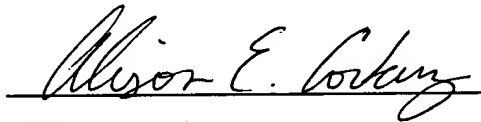
Applicants respectfully request that the rejection with regard to these claims be reconsidered and withdrawn.

CONCLUSIONS

In view of the arguments set forth above, Applicants respectfully submit that the rejections contained in the Office Action mailed on September 21, 2004, have been overcome, and that the claims are in condition for allowance. If the Examiner believes that any further discussion of this communication would be helpful, he is invited to contact the undersigned at the telephone number provided below.

No fees are believed to be due in connection with this response. However, please charge any underpayments or credit any overpayments to Deposit Account No. 08-0219.

Respectfully submitted,



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